# EC-CERTIFICATE

## (Full quality assurance system)

This is to certify that the company

## REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Traumatological Implants and Instruments for HF-Surgery, Endoscopes and accessories according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

| | |
|---|---|
| Certificate registration no. | 070894 MR2 |
| Certificate unique ID | 170622161 |
| Effective date | 2015-05-17 |
| Expiry date | 2020-05-16 |
| Frankfurt am Main | 2015-05-14 |

Digitally signed by Iarovoi Petru
Date: 2019.07.31 16:32:38 EEST
Reason: MoldSign Signature
Location: Moldova

**DQS Medizinprodukte GmbH**

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, info@dqs-med.de

**DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.**



20120803/2/EN380308

**Declaration of Conformity**

REDA INSTRUMENTE GMBH

# Konformitätserklärung
# *Declaration of Conformity*


## REDA INSTRUMENTE GMBH
Gänsäcker 34
78532 Tuttlingen / Germany
Tel.: +49 (0)74 62 / 9445-0
Fax: +49 (0)74 62 / 9445-20
e-Mail: info@reda-instrumente.de


erklärt hiermit unter eigener Verantwortung, dass alle Artikel der Produktgruppe
*herewith declare under our own responsibility, that all items of the product group*

**Instrumente und Geräte für die Chirurgie der Klasse I, IIa + IIb**
gemäß unseren Katalogen Standard Chirurgische Instrumente, Titan Instrumente, HF Monopolar und Bipolar, Neuro Chirurgie Instrumente, Dental Instrumente,
Steril Container, Endoskope und Zubehör für flexible und starre Endoskopie

***Instruments and Equipment for surgery of Class I, IIa + IIb***
in refer to our catalogues General Surgical Instruments, Titanium Instruments, Neuro Surgery Instruments, Dental Instruments, HF Monopolar and Bipolar,
Sterilization Containers, Endoscopes and Accessories for flexible and rigid Endoscopy

klassifiziert gemäß RL 93/42/EWG (M5), Anhang IX, Regel 1, 6, 7 und 11 in Risikoklasse I, IIa + IIb
*classified according to MDD 93/42/EEC (M5) annex IX rule 1, 6, 7 and 11 into risk class I, IIa + IIb*

unter Berücksichtigung folgender Richtlinie gefertigt wurden:
*have been manufactured under consideration of following Council Directive:*

**EG-Richtlinie 93/42/EWG (M5)**
***European Medical Device Directive 93/42/EEC (M5)***

Angewandtes Konformitätsbewertungsverfahren nach Richtlinie 93/42/EWG (M5), Anhang II.
Die gelisteten Produkte sind konform mit den Grundlegenden Anforderungen des Anhang I der EG-Richtlinie 93/42/EWG (M5) und werden somit

mit CE bzw CE 0297 gekennzeichnet, von uns in Verkehr gebracht
Das Konformitätsbewertungsverfahren der Klassen IIa und IIb wurde durch unsere Benannte Stelle DQS GmbH, Frankfurt, Notified Body Code 0297 durchgeführt.

*Applied conformity assessment according Annex II of MDD 93/42/EEC (M5).*
*The listed products are conform to the essential requirements of the Medical Device Directive 93/42/EEC (M5) Annex I and are therefore placed into market*

*with* CE *or with* CE 0297 *by us.*

*The conformity assessment for class IIa and IIb has been performed by our notified body DQS GmbH, Frankfurt, notified body code 0297.*

***Tuttlingen, December 2018***

Regina Hehl
Geschäftsführerin
Managing Director

Thomas Bends
Quality Manager

Diese Erklärung ist gültig bis 2020-05-16 / This declaration is valid until 2020-05-16

# CERTIFICATE

This is to certify that the company

## REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Manufacturing and distribution of sterile surgical instruments and manufacturing and distribution of non-active medical devices for endoscopy, orthopedics, RF-electrodes, drills and accessories.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## EN ISO 13485 : 2016

| | |
|---|---|
| Certificate registration no. | 070894 MP2016 |
| Certificate unique ID | 170704009 |
| Effective date | 2018-05-17 |
| Expiry date | 2021-05-16 |
| Frankfurt am Main | 2018-05-08 |

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

**DQS Medizinprodukte GmbH**

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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